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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/816,790 | 03/22/2001 | Keith D. Allen | R-855 | 5557 |

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| EXAMINER |
|---|
| QIAN, CELINE X |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1633 | 7 |

DATE MAILED: 12/03/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/816,790 | ALLEN ET AL. | |
| | Examiner | Art Unit | |
| | Celine Qian | 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Claims 1-25 are pending in the application.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 17-21, drawn to a targeting construct, a method of making said targeting construct, a cell comprising a disruption in a sulfontransferase gene, a sulfontransferase gene knockout non-human animal and a method of making said non-human animal, classified in class 536, subclass 230.1, class 435, subclass 91.41, class 800, subclass 13 and 21.

II. Claims 11 and 13, drawn to a method of identifying an agent that modulates sulfontransferase gene expression, classified in class 800, subclass 3.

III. Claims 12, 14 and 23, drawn to a method of identifying an agent that modulates sulfontransferase gene function, classified in class 800, subclass 3.

IV. Claim 16 and 25, drawn to an agent that modulates sulfontransferase gene expression or function, classified in class 800, subclass 3.

V. Claims 22 and 24, drawn to a method of identifying an agent that ameliorate a behavior associated with a disruption in a sulfontransferase gene, classified in class 800, subclass 3.

VI. Claim 25, drawn to an agent that modulates a behavior associated with sulfontransferases disruption, classified in class 800, subclass 3.

Claim 15 is generic to groups II and III. Claim 25 is generic to groups IV and VI. The generic claims will be examined in so far as it reads on the elected subject matter.

The inventions are distinct, each from the other for the following reasons:

Inventions I and II are patentably distinct because the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operation. The DNA construct of Group I is not required for the method of Group II. The method of making a sulfontransferase knockout animal involves different steps than the method of identifying a sulfontransferase expression modulator. Although the transgenic animal of Group I can be used in the method of Group II, it is not limited to this use. It can also be used to study the phenotype of sulfontransferase disruption. Thus, the inventions of Group I are patentably distinct from the inventions of Group II.

Inventions I and III are patentably distinct because the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operation. The DNA construct of Group I is not required for the method of Group III. The method of making a sulfontransferase knockout animal involves different steps than the method of identifying a sulfontransferase function modulator. Although the transgenic animal of Group I can be used in the method of Group III, it is not limited to this use. It can also be used to study the phenotype of sulfontransferase disruption. Thus, the inventions of Group I are patentably distinct from the inventions of Group III.

Inventions I and IV are patentably distinct because the inventions are drawn to materially different compositions and methods that are not directly related. The DNA construct and transgenic animal of Group I are chemically, biologically, and functionally distinct from the sulfontransferase expression/function modulator of Group IV. The method of making DNA

construct and knockout animal does not require the agent of Group IV. Thus, the inventions of Group I are patentably distinct from the inventions of Group IV.

Inventions I and V are patentably distinct because the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operation. The DNA construct of Group I is not required for the method of Group V. The method of making a sulfontransferase knockout animal involves different steps than the method of identifying an agent capable of ameliorate a behavior that associated with sulfontransferase disruption. Although the transgenic animal of Group I can be used in the method of Group V, it is not limited to this use. It can also be used to study the phenotype of sulfontransferase disruption. Thus, the inventions of Group I are patentably distinct from the inventions of Group V.

Inventions I and VI are patentably distinct because the inventions are drawn to materially different compositions and methods that are not directly related. The DNA construct and transgenic animal of Group I are chemically, biologically, and functionally distinct from the agent of Group VI. The method of making DNA construct and knockout animal does not require the agent of Group VI. Thus, the inventions of Group I are patentably distinct from the inventions of Group VI.

Inventions II and III are patentably distinct because the inventions are drawn to methods that require different starting material and modes of operation. The method of identifying a sulfontransferase expression modulator involves different steps than the method of identifying a sulfontransferase function modulator. Thus, the inventions of Group II and III are patentably distinct.

Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the agent of Group IV can also be identified by other method, e.g. contacting a wild type cell with the agent and measure the sulfontransferase expression. Thus, the inventions of Group II are patentably distinct from the inventions of Group IV.

Inventions II and V are patentably distinct because the inventions are drawn to methods that require different starting material and modes of operation. The method of identifying a sulfontransferase expression modulator involves different steps than the method of identifying an agent that ameliorate a phenotype associated with sulfontransferase disruption. Thus, the inventions of Group II and V are patentably distinct.

Inventions II and VI are patentably distinct because the inventions are drawn to methods and compositions that are not directly related. The methods of Group II cannot produce the agents of Group VI. Thus, the inventions of Group II and VI are patentably distinct.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the agent of Group IV can also be identified by other method, e.g. contacting a wild type cell with the agent and determine whether sulfontransferase activity is modulated. Thus, the inventions of Group III are patentably distinct from the inventions of Group IV.

Inventions III and V are patentably distinct because the inventions are drawn to methods that require different starting material and modes of operation. The method of identifying a modulator of sulfontransferase function involves different steps than the method of identifying an agent that ameliorate a phenotype associated with sulfontransferase disruption. Thus, the inventions of Group III and V are patentably distinct.

Inventions III and VI are patentably distinct because the inventions are drawn to methods and compositions that are not directly related. The methods of Group III cannot produce the agents of Group VI. Thus, the inventions of Group III and VI are patentably distinct.

Inventions IV and V are patentably distinct because the inventions are drawn to compositions and methods that are not directly related. The methods of Group V cannot produce the agents of Group VI. Thus, the inventions of Group IV and V are patentably distinct.

Inventions IV and VI are patentably distinct because the inventions are drawn to materially distinct compositions. The agents of Group IV are chemically, biologically and functionally distinct from the agent of Group VI. Thus, the inventions of Group IV are patentably distinct from the inventions of Group VI.

Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the agent of Group VI can also be identified by other method, e.g. administering the agent to a hyperactive mouse and determine whether the hyperactive behavior is ameliorated. Thus, the inventions of Group V are patentably distinct from the inventions of Group VI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0823. The examiner can normally be reached on 8:30-5:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J Clark can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D
November 28, 2001

REMY YUCEL, PH.D
PRIMARY EXAMINER